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Applicant(s):	Orhun K. MURATOGLU *et al.*	Confirmation No.: 3038
Serial No.:	10/757,551	Examiner: S. Staicovici
Filing Date:	January 15, 2004	Group Art Unit: 1732
Title:	METHODS FOR MAKING OXIDATION RESISTANT POLYMERIC MATERIAL	

MAIL STOP RCE
Commissioner for Patents
U.S. Patent and Trademark Office
PO Box 1450
Alexandria, Virginia 22331-1450

DECLARATION OF ORHUN K. MURATOGLU

I, Orhun K. Muratoglu, do hereby declare as follows:

1. I received my Ph.D. in Materials Science and Engineering, Program in Polymer Science and Technology, from the Massachusetts Institute of Technology ("MIT") in 1995. I have been engaged in the study of polymers, such as ultra high molecular weight polyethylene (UHMWPE), for use in prosthetic devices for over ten years. I have authored or co-authored at least 35 peer-reviewed papers and 21 book chapters and review articles concerning UHMWPE and its use in medical prosthetics. I am currently employed by the Massachusetts General Hospital and a co-inventor named in the captioned patent application.

2. I understand that the claims in the captioned patent application have been rejected over various patents. The examiner has noted in the advisory Action issued February 21, 2006, that it is not clear whether the improvement in wear is due to an increased vitamin E concentration or due to doping of the consolidated polyethylene. In response to the examiner's commentary, I submit the following:

3. The pin-on-disk wear behavior of conventional UHMWPE, UHMWPE plus α-tocopherol doped, irradiated UHMWPE, and irradiated plus α-tocopherol doped UHMWPE was investigated to determine if the presence of α-tocopherol affected the wear properties of UHMWPE. The following methods were employed:

Materials and Methods

The pin-on-disk test samples were cylindrical pins (9mm diameter, 13 mm height).

The UHMWPE test samples were machined from GUR1050 UHMWPE stock.

Another group of conventional UHMWPE test samples were machined from GUR1050 UHMWPE stock and then doped with α-tocopherol for 1 hour at 120°C followed by 24 hours of homogenization at 120°C.

The irradiated UHMWPE test samples were machined from 85 kGy gamma irradiated and annealed GUR1050 UHMWPE stock.

Another group of irradiated UHMWPE test samples were machined from 85 kGy gamma irradiated GUR1050 UHMWPE stock. The irradiated test samples were doped with α-tocopherol for 2.5 hours at 120°C followed by 16 hours of homogenization at 120°C.

Three samples from each group were tested on the bi-directional POD (n=3).

α-Tocopherol concentration profiles were determined by using FTIR spectroscopy. A bidirectional pin-on-disk wear tester was used to measure the wear rate of UHMWPE specimens articulating against polished cobalt-chrome lubricated by bovine serum.

The bidirectional motion was produced by a computer-controlled XY table which was programmed to move in a 10mm x 5mm rectangular pattern. Each test was conducted at 2Hz for 2 million cycles.

The lubricant used for the study was 100% bovine serum, stabilized with 10.7 millimoles of ethylenediamine tetraacetate (EDTA, Fisher Scientific, Pittsburgh, PA) and 33 ml of penicillin-streptomycin solution (Sigma-Aldrich, St. Louis, MO) per 500 ml of serum.

The wear rate was calculated by the linear regression slope of weight loss versus number of cycles. Statistical analysis was performed on the wear rates by using a student's t-test.

4. The investigation produced the following results and lead to the following conclusions:

Results and Conclusions

The average mass loss as a function of sliding cycles for each material type is shown in Figure 1 below. Table 1 below shows the average wear rate with standard deviation for each type of tested pin.

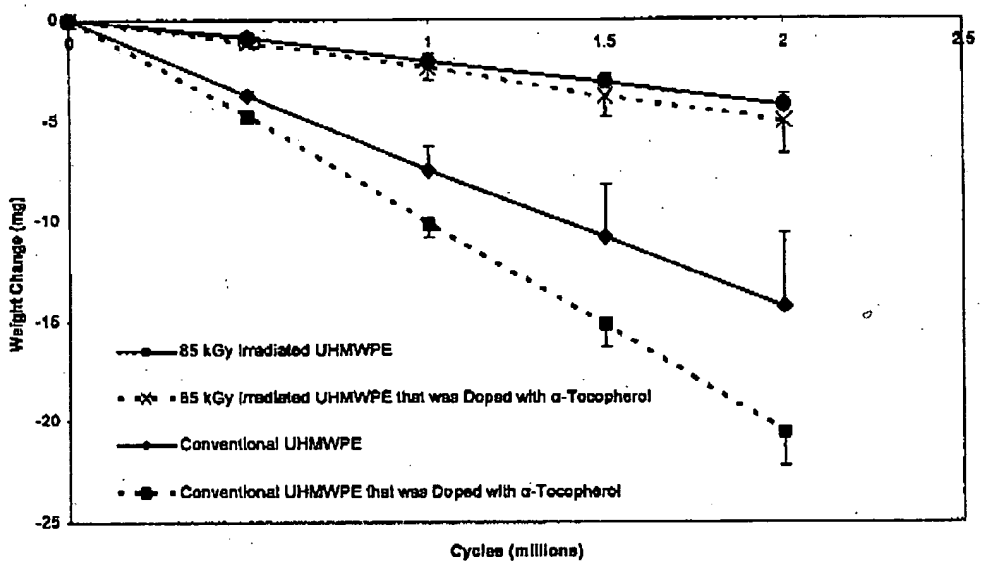

Figure 1: Average weight loss of each test sample (n=3 for each group) over 2 million cycles of testing shown with standard deviation error bars.

Table 1: The average wear rate of the test groups studied (n=3).

UHMWPE	Wear Rate (mg/MC)	p-value
Conventional UHMWPE	7.12 ± 1.93	0.09
Conventional UHMWPE Doped with α-Tocopherol	10.3 ± 0.83	
85 kGy Irradiated UHMWPE	2.15 ± 0.28	0.27
85 kGy Irradiated UHMWPE Doped with α-Tocopherol	2.58 ± 0.80	

The wear rate of the conventional UHMWPE was 7.12 ± 1.93 mg/MC. The conventional UHMWPE that was doped with α-tocopherol had a wear rate of 10.3 ± 0.83mg/MC. A student's t-test was used to compare these two results and a p-value of 0.09 was calculated indicating that these two groups are not statically significant and that the α-tocopherol does not statistically alter the wear rate of conventional UHMWPE.

The wear rate of the 85 kGy irradiated UHMWPE was 2.15 ± 0.28 mg/MC. The 85 kGy irradiated UHMWPE that was doped with α-tocopherol had a wear rate of 2.85 ± 0.80 mg/MC. A student's t-test was used to compare these two results and a p-value of 0.27 was calculated indicating that these two groups are not statistically significant and that the α-tocopherol does not statistically alter the wear rate.

In summary, the α-tocopherol-doped UHMWPE, either irradiated or virgin does not have a statistically different wear rate than the corresponding non-doped UHMWPEs. Therefore it is concluded that the α-tocopherol itself has no direct effect on the wear resistance of α-tocopherol-doped, irradiated UHMWPE.

5. The purpose of the α-tocopherol, such as vitamin E, is to resist oxidation of the doped polymer, such as UHMWPE. Wear resistance, on the other hand, is imparted to the polymer via cross-linking through processes such as irradiation. In fact, as explained at page 35, lines 3-7 of the specification, α-tocopherol can actually interfere with the process of cross-linking when the α-tocopherol is mixed with UHMWPE powder prior to irradiation.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

4/21/06
Date

Orhun K. Muratoglu, Ph. D.